UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 2666 (JNE/FLN)
This Document Relates to **ALL ACTIONS**	

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' EXPERT DR. YADIN DAVID

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INTRODUCTION

Defendants 3M Company and Arizant Healthcare (collectively "Defendants") move this Court to exclude the testimony of Plaintiffs' expert, Yadin David, Ed.D, P.E., C.C.E, (1) in the federal multi-district litigation ("MDL") proceedings, pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993); and (2) in the Minnesota state proceedings, pursuant to Minnesota Rule of Evidence 702 and the *Frye-Mack* standard of admissibility. Dr. David is a biomedical engineer who purports to opine that Defendants violated various regulations and industry standards in its marketing of the Bair Hugger™ patient warming system ("Bair Hugger system"), that use of the Bair Hugger system in orthopedic surgeries increases the risk of surgical site infections ("SSIs"), and that alternative patient-warming technologies exist that are safer. Defendants also anticipate Dr. David will attempt to testify to the motives, intent, and state of mind of Defendants if permitted. Defendants move to exclude these opinions on the following grounds:

- **Regulatory Opinions.** As at least one other court has concluded, Dr. David is not qualified to opine on regulatory matters. *See Stevens v. Stryker Corp.*, No. 12-cv-63-bbc, 2013 WL4758948, at *4 (W.D. Wis. Sept. 4, 2013). Moreover, his opinions that Defendants violated various federal statutes and regulations are improper legal conclusions, and Plaintiffs cannot use Dr. David at trial to recite the contents of their favorite documents and testimony under the guise of a "regulatory opinion."

- **Medical Device Industry Standard Opinions.** Dr. David is an outsider to the device industry, and unqualified to opine to industry standards. The "hazard

analysis" that he contends Defendants should have undertaken prior to marketing the Bair Hugger system is not even based on a scientifically reliable framework that addresses medical device design.

- **"Hazard Analysis" Opinions.** Dr. David purports to have performed a "hazard analysis" of the Bair Hugger system, but lacks the design expertise to properly perform such an analysis, and failed to employ the scientifically accepted analytical framework. Moreover, while Dr. David claims to offer causation opinions based on his work, he fails to explain how a "hazard analysis" conducted by a biomedical engineer with no clinical expertise is a reliable method to reach such conclusions. At most, his opinions are based upon the same deficient articles that Plaintiffs' other engineering experts rely upon, which do not establish causation; and they ignore the conclusion of every reputable medical organization addressing the issue, including the Food and Drug Administration ("FDA"), that there is no proof of an increased risk of SSIs with use of the Bair Hugger.

- **Alternative Design Opinions.** Dr. David makes no showing whatsoever that any of his proposed alternative designs are actually safer, or that their safety characteristics could be integrated into the Bair Hugger without affecting its function. That is unsurprising because, before his retention in this case, Dr. David had virtually no knowledge of the Bair Hugger system, or of any other patient-warming technologies he now claims are safer alternatives.

- **Motive, Intent, and State of Mind Opinions.** Courts have universally rejected such testimony as speculative and unhelpful to the jury.

For all of these reasons, as discussed in greater detail below, the Court should exclude Dr. David's opinions in their entirety.

BACKGROUND

Dr. David's primary opinions can be boiled down to five: (1) that the regulatory history for the Bair Hugger system is "troubling" and that Defendants violated 21 U.S.C. § 301 and various FDA regulations in marketing the product (David Rpt. (ECF No. 316) at 17, 43); (2) that Defendants violated industry standards in marketing the Bair Hugger system (David Rpt. at 44); (3) that use of the Bair Hugger system is "more likely than not contributing to infections during orthopedic implant surgeries" (David Rpt. at 1, 8); (4) that feasible alternative designs exist that are safer than the Bair Hugger system (David Rpt. at 32-43); and (5) opinions related to Defendants' intent, motive, or state-of mind.

Dr. David claims to have reached his opinions based on a "hazard analysis" of the Bair Hugger system, comprised of the following components:

- **His review of a total of sixty-four (64) 3M/Arizant-produced documents.** Dr. David inspected a total of 64 documents produced by Defendants (out of the millions of pages produced in this action). (David Rpt., at 46-47; *see also* Indexes of Materials Reviewed by Dr. David (Ex. 1).) These documents were selected by Plaintiffs' counsel in response to much broader requests for materials by Dr. David. (2017-08-01 Yadin David Deposition Transcript ("David Dep.") at 165:14-167:6 (Ex. 2).)[1]

[1] Dr. David testified unambiguously these were the only company documents he reviewed. (*See* David Dep. at 163:25-167:6, 177:13-180:11.) Nevertheless, at the conclusion of his deposition, Plaintiffs' counsel asked leading questions in an effort to establish he also reviewed exhibits to nine depositions, which may have included more documents than the 64 in the notebook he brought to his deposition; and then ended the

- **His review of nine (9) deposition transcripts and three (3) of Plaintiffs' other expert reports**. (David Rpt., at 46, 49.)

- **His review of fourteen (14) published articles, and a small selection of websites and other publicly available documents.** (David Rpt., at 48-51.)[2]

- **His inspection of a used Bair Hugger system.** Plaintiffs' counsel purchased a Bair Hugger system from eBay.com that had been previously used by unknown parties, for an unknown length of time, and under unknown circumstances. (*See* David Dep. at 33:16-34:19, 121:3-8.) Dr. David testified the purpose of this examination was merely to gain familiarity with the device, and was not intended to replicate clinical conditions or to support clinical opinions. (David Dep. at 23:20-23, 27:10-18, 39:25-40:10, 119:2-121:11.)

Dr. David vaguely recalls seeing a "Bair Hugger product" in an inpatient room "one or two times" in the late 1990's, but otherwise had no exposure to the Bair Hugger system prior to his involvement in this case. (David Dep. at 11:4-17, 17:20-19:24, 20:5-8.) He recalls no discussion about Bair Hugger systems during his work at any hospital (David Dep. at 19:15-24); has never researched, published or presented on the Bair Hugger system (David Dep. at 201:22-202:16); and cannot recall ever evaluating or operating a Bair Hugger system other than the one he examined in the context of this case (David Dep. at 13:18-25, 17:3-19, 23:2-10). Similarly, prior to his work in this case,

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deposition without permitting further follow-up. (David Dep. at 321:9-324:15.) Even if Dr. David did review some of the deposition exhibits as Plaintiffs' counsel led him to testify, the scope of documents he reviewed remains a small counsel-selected subset of Defendants' total production, and only a fraction of what Tim Ulatowski accessed.

[2] In contrast, Defendants' regulatory expert Dr. Tim Ulatowski had access to a thorough record in forming his opinions, including more than 75,000 pages of 3M/Arizant-produced documents, forty-four deposition transcripts, and more than 250 relevant articles, among numerous other materials.

Dr. David had never examined or evaluated any of the other patient-warming devices he now contends to be feasible alternative designs. (David Dep. at 159:5-160:23.)

Nevertheless, Dr. David claims to be qualified to render his opinions in this case as a result of his biomedical engineering background, and his experience as Director of the Biomedical Engineering Department and chairman of the Medical Technology Evaluation Committee at Texas Children's Hospital, where he has sat on a committee that evaluates medical devices in order to make purchasing recommendations on behalf of the hospital. (David Rpt. at 4; David Dep. at 305:24-307:14.) But his experience in these roles is disconnected from the opinions he offers. For example, while Dr. David purports to opine on alleged risks associated with the Bair Hugger system *in the clinical setting* (David Rpt. at 8), he concedes that he is not a clinician, and that he does not in his professional capacity assess clinical benefit or risk on his own, but rather relies upon medical doctors and nurses to assess such factors. (David Dep. at 306:20-307:1, 307:3-9, 309:3-7 (conceding he "rel[ies] on physicians and nurses to provide [him] with information about clinical risks and benefits" in performing his work for hospitals).)

Moreover, Dr. David's testimony establishes that, prior to his work in this litigation, he had never independently made the type of regulatory conclusions he purports to reach here. Although he has in the past sat on a handful of FDA advisory panels, his role on those panels has been to provide perspective on discrete issues based on his "unique combination" of expertise—that is, the "[biomedical] engineering and the clinical exposure and appreciation for processes involv[ing] technology in [the] patient care environment." (David Dep. at 187:21-188:7.) He has not come to regulatory

conclusions on his own, or even applied the regulations that he purports to apply in the context of the Bair Hugger system. (*See* David Dep. at 189:20-190:2, 191:20-192:16.)

THE COURT SHOULD EXCLUDE DR. DAVID IN THE FEDERAL MDL PROCEEDINGS

For the reasons discussed below, the Court should exclude Dr. David's opinions entirely in the federal MDL proceedings.[3]

I. The Court Should Exclude Dr. David's Regulatory Opinions.

In his Report, Dr. David purports to analyze the "troubling" regulatory history of the Bair Hugger. In essence, he summarizes the contents of select documents he reviewed, and claims to reach "regulatory opinions" based upon them. Among other things, he claims that the Defendants' 510(k) submissions seeking clearance of the Bair Hugger system did not demonstrate the required "substantial equivalence" to be cleared, and in fact misled the FDA. He also claims the Bair Hugger system is "adulterated" and "misbranded" in violation of the Federal Food, Drug and Cosmetic Act ("FDCA"); and that Defendants violated other FDA regulations by failing to satisfy Good Manufacturing Practices, and by failing to perform an adequate safety validation prior to marketing the product. (*See generally* David Rpt. at 43-45 (ECF No. 316).)

The Court should exclude Dr. David's regulatory opinions, first, because he lacks the necessary qualifications. Second, Dr. David's contentions that Defendants violated the FDCA and sold "adulterated" and "misbranded" products are impermissible legal

[3] The legal principles governing the *Daubert* inquiry are laid out fully in Defendants' concurrently filed motion to exclude Plaintiffs' medical experts, and are fully incorporated by reference herein.

conclusions. Third, much of Dr. David's regulatory "opinions" simply narrate documents that the jury needs no help in interpreting, rendering his testimony unhelpful, and inadmissible under Rule 702. For all of these reasons, as discussed more thoroughly below, the Court should exclude Dr. David's regulatory opinions in their entirety.

A. Dr. David is Not Qualified to Opine on Regulatory Issues.

Dr. David claims to reach regulatory opinions related to both (a) initial 510(k) clearance, *i.e.*, substantial equivalence, and (b) post-clearance regulation, *i.e.*, compliance with Quality System Regulations and prohibition of adulterated or misbranded devices. (*See* David Rpt. at 17-27, 43-45.) He is not qualified to opine on either aspect.

Dr. David is a biomedical engineer by training. (David Rpt., at 3.) He is not a medical doctor, and has no medical background. (David Dep. at 247:13-16.) He is not a design engineer, and has never even reviewed a design history file. (David Dep. at 167:7-12.) He also has never worked for the FDA. (David Dep., at 181:15-182:5; *see also id.* at 181:24-182:5, 189:17-19.) Although he has in the past sat on a handful of FDA advisory panels—some of which were convened to evaluate 510(k) applications—his role was not to make regulatory or "substantial equivalence" determinations himself, but rather, to provide perspective on discrete issues posed by the FDA based on his biomedical engineering background. (David Dep. at 187:21-188:7.)

With regard to post-clearance regulatory matters, Dr. David has even less experience. He concedes he has never had any input into any FDA compliance decision, nor has he ever been consulted with respect to whether a device was "adulterated" or "misbranded." (David Dep. at 189:20-190:2.) Indeed, when asked whether he had ever

even applied the terms "adulterated" or "misbranded" outside of litigation, Dr. David responded: "No. I'm not involved in the legal profession." (David Dep. at 191:20-192:16.) In short, Dr. David has never reached regulatory conclusions on his own—related either to clearance or post-clearance matters—nor has he ever applied the regulations that he purports to apply now in the context of the Bair Hugger system.

At least one other court has recognized that Dr. David is not qualified to opine on regulatory matters, and excluded his testimony on the subject entirely. *See Stevens*, 2013 WL4758948, at *4. In *Stevens*, Dr. David opined to various alleged regulatory violations, just as he does here. The Court excluded these opinions, observing: "David's report consists of nothing but a list of regulations and conclusions that defendants violated them, along with a narrative of historical facts that does not require an expert to interpret. I agree with defendants that nothing in David's report suggests that he is a regulatory expert (he is a biomedical engineer). . . ." *Id.* The reasoning of the *Stevens* court applies with equal force here. The Court should exclude his regulatory testimony in its entirety.

B. Dr. David's Regulatory Opinions Are Impermissible Legal Conclusions

Dr. David's regulatory opinions that Defendants violated the FDCA, and marketed Bair Hugger products that were "adulterated" and "misbranded," are additionally inadmissible as improper legal conclusions.

As this Court has recognized, expert opinions that merely offer legal conclusions "inappropriately supplant 'the judgment of the district court.'" *Longlois v. Stratasys, Inc.*, 88 F. Supp. 3d 1058, 1063 (D. Minn. 2015) (precluding regulatory expert from opining that a party had violated the Fair Labor Standards Act). It is for the court, not the experts,

to state the law for the jury. *See Kruszka v. Novartis Pharms. Corp.*, 28 F. Supp. 3d 920, 934 (D. Minn. July 1, 2014) ("[A]ttempts by [plaintiff's expert] to offer an opinion as to whether [defendant] violated the law with respect to the FDA constitute a legal conclusion and are not admissible."); *see also U.S. v. Scholl*, 166 F.3d 964, 973 (9th Cir. 1999); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004).

While courts have admitted expert testimony regarding FDA regulations generally and a defendant's compliance therewith as evidence related to the applicable standard of care, *see In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 191 (S.D.N.Y. 2009) ("A lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care in the pharmaceutical industry."), courts frequently preclude experts from opining that a defendant "violated the law with respect to FDA" or that a product is "adulterated" or "misbranded" for purposes of the FDCA, recognizing that *even the FDA lacks authority* to make such determinations on its own. *See Kruszka*, 28 F. Supp. 3d at 934 ("[A]ttempts by [Plaintiffs' expert] to offer an opinion as to whether [Defendant] violated the law with respect to the FDA constitute a legal conclusion and are not admissible."); *In re Zimmer NexGen Knee Implant Prod. Liab. Litig.*, No. 12-C-6279, 2015 WL 5145546, at *18 (N.D. Ill. Aug. 31, 2015); *see also Wyeth v. Levine*, 555 U.S. 555, 570 (2009) ("[B]ecause the statute contemplates that federal juries will resolve most misbranding claims, the FDA's belief that a drug is misbranded is not conclusive").

Here, Dr. David offers in his Report several opinions that are pure legal conclusions that Defendants violated the FDCA. These include, *inter alia*:

- "It is my opinion that the Defendant violated Section 301 of the Food & Drug Act, which prohibits selling a medical device in the United States that is not safe and adequately labeled. *See* 21 U.S.C. § 331."

- "[T]he device is misbranded because its labeling fails to contain adequate instructions for use including appropriate warnings."

- The Defendants violated 21 U.S.C. § 301 by (1) "[t]he introduction . . . into interstate commerce of any device that is adulterated or misbranded," (2) "[t]he adulteration or misbranding of any device in interstate commerce," (3) [t]he receipt in interstate commerce of nay device that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise," (4) "[t]he manufacture . . . of any device that is adulterated or misbranded," and (5) "[w]ith respect to any device, the submission of any report that is required by or under [the FDCA] that is false or misleading in any material respect."

(*See* David Rpt. at 43-45.) The Court should exclude these opinions.

C. Dr. David May Not Serve as Narrator in Chief of Plaintiffs' Case

Significant blocks of Dr. David's Report, including the entirety of Sections 5 and 7, consist of nothing more than recitations of the contents of Plaintiffs' favorite documents and snippets of Plaintiffs' favorite testimony. If Dr. David's Report is any indication, Plaintiffs will call Dr. David at trial to present a narrative history of the Bair Hugger system and the Defendants' regulatory interactions with the FDA, in an attempt to convey the Plaintiffs' theories in this case in a manner akin to a closing argument. This tactic is improper. *See In re Fosamax*, 645 F. Supp. 2d at 192 (precluding expert from testifying to "a narrative of select regulatory events through the summary or selective quotation from internal [company] documents, regulatory filings, and the deposition testimony of [company] employees"); *In re Zimmer NexGen*, 2015 WL 5145546, at *12 (excluding expert who "simply summarize[d] internal [manufacturer] documents regarding post-market surveillance").

Plaintiffs in other cases have attempted this approach with Dr. David, unsuccessfully. As discussed above, the Court in *Stevens v. Stryker* excluded Dr. David based on the following reasoning:

> In my view, David's report consists of nothing but a list of regulations and conclusions that defendants violated them, along with **a narrative of historical facts that does not require an expert to interpret**. I agree with defendants that nothing in David's report suggests that he is a regulatory expert (he is a biomedical engineer), but even if he were, **plaintiff has not shown how his testimony would be helpful to the jury.**

Stevens, 2013 WL4758948, at *4 (emphasis added).

Other courts have done the same with different experts—routinely excluding the very sort of testimony that plaintiffs proffer from Dr. David here. *See, e.g.*, *In re Viagra Products Liability Litigation*, 658 F. Supp. 2d 950, 967 (D. Minn. 2009) (excluding regulatory expert's chronology of regulatory events); *In re Fosamax*, 645 F. Supp. 2d at 192 (excluding testimony of expert who offered narrative history of product and FDA submissions, who would "merely read, selectively quote from, or 'regurgitate' the evidence."); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 478 (S.D.N.Y. Mar. 8, 2016); *Ocasio v. C.R. Bard, Inc.*, No. 8:13-CV-1962, 2015 WL 2062611, at *4 (M.D. Fla. May 4, 2015) ("regardless of the accuracy of [the expert's] characterization, … such testimony must be excluded because 'an expert cannot be presented to the jury [ ] for the purpose of constructing a factual narrative based upon record evidence.'"); *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1330 (M.D. Fla. 2015) (excluding expert's opinions that offered "plaintiff-slanted summaries of [manufacturer] documents," stating that it would "not permit [the expert] to testify 'to simple inferences

drawn from uncomplicated facts that serve only to buttress plaintiff's theory of the case.'"); *In re Zimmer NexGen*, 2015 WL 5145546, at *12; *Wells v. Allergan, Inc.*, 2013 WL 7208221, at *2 (W.D. Okla. Feb. 4, 2013); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 628 (S.D. W.Va. 2013).

Plaintiffs essentially want Dr. David to summarize their favorite facts, draw the most favorable inferences based on those facts, and effectively deliver a closing argument in the middle of trial. There are two obvious problems with this tactic. First, closing argument is routinely preceded by an admonition from the Court that it is *not evidence*. Allowing a closing argument under the guise of expert testimony would convert a non-evidentiary closing argument into substantive evidence. Second, allowing summation by an *expert* is particularly dangerous because the expert wears a cloak of credibility. If Dr. David were allowed walk the jury through plaintiffs' cherry-picked documents, the jury naturally could presume his expertise offers special insights they do not have. *See U.S. v. Hall*, 93 F.3d 1337, 1343 (7th Cir. 1996) ("Unless the expertise adds something, the expert is at best offering a gratuitous opinion, and at worst is exerting undue influence on the jury that would be subject to control under Rule 403."); *Baldonado v. Wyeth*, No. 04-C-4312, 2012 WL 1802066, at *4 (N.D. Ill. May 17, 2012) ("allowing an expert to provide summary testimony 'based on nothing more than [the expert's] review of certain discovery materials could give the jury the impression that he did something more than simply review the materials, which the jury can do itself.'").

Dr. David does not possess the necessary qualifications to testify to complex regulatory issues, nor does he bring substantive expertise in filter technology, operating

room ventilation, or clinical assessments of infection risk. He should not be permitted to simply read documents that the jury needs no assistance to interpret. The Court should exclude Dr. David's regulatory opinions in their entirety.[4]

II. The Court Should Exclude Dr. David's Opinions as to the Medical Device Industry Standard of Care.

Dr. David purports to opine on the standard of care in the medical device industry, proclaiming what a "reasonably prudent medical device manufacturer" would do. (*See, e.g.*, David Rpt. at 5, 44 (ECF No. 316); David Dep. at 264:2-17.) Dr. David is not qualified to render such opinions, and such testimony should be excluded in its entirety.

It is widely recognized that "the area of the witness's competence [must] match[] the subject matter of the witness's testimony." *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1101 (8th Cir. 2006); *see also Wheeling Pitt. Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715-16 (8th Cir. 2001) (district court abused discretion in permitting hydrologist to testify about safe warehousing practices, an area outside of his expertise). Here, while Dr. David may be an accomplished biomedical engineer with experience as a member of a *hospital committee* evaluating medical technology, and as a *customer* to medical device manufacturers, he is very much an *outsider* to the medical device industry. He has never designed a medical device, let alone a patient warming device, and has never reviewed a design history file. (David Dep. at 167:7-12, 201:22-24.) He is not familiar with any industry guidelines or standards applicable to the

[4] To the extent any of Plaintiffs' other experts seek to testify about 3M or Arizant documents under the guise of expert opinion, their testimony should also be excluded for the reasons discussed above.

medical device design process. (David Dep. at 168:17-24, 229:10-14.) And while he purports to understand industry "guidelines" and "accepted practice" as to risk assessments for medical devices, when pressed, he referred to a standard (MITRE) related to the evaluation of a *system*, not a medical device, which he has used in the past for *disaster preparedness* in a hospital setting (for example, if the electrical grid were to go down), as opposed to the risk assessment for medical devices from a manufacturer's perspective. (*See* David Dep. at 169:8-172:13.) And when asked about ISO standard 14971—the standard that governs risk management for medical devices—Dr. David testified that, while he has "worked with it" and is "aware of it," he has never applied it, and did not consult that standard in his evaluation in this case:

> Q. What is ISO 14971? What is it intended -- what is it? What does it apply to?
> A. It's basically quality system organization.
> Q. I'm sorry. ISO Standard specifically 14971, do you know what that addresses?
> A. It's addressed risk management.
> Q. For what?
> A. For medical devices.
> Q. Did you consult that in connection with your work in this case?
> A. No, I don't believe so.
> Q. You are aware of it?
> A. I am.

(David Dep. at 173:7-22; *see also id.* at 172:19-23.)

Courts have frequently precluded industry outsiders, like Dr. David, from testifying to industry standard opinions. *See, e.g.*, *Kruszka*, 28 F. Supp. 3d at 935 ("[T]o the extent Dr. Parisian attempts to opine on whether Novartis acted according to the regular practices of pharmaceutical companies outside of FDA regulations, Dr. Parisian is

not qualified and any such testimony would be unreliable. Dr. Parisian is an expert on the FDA, not on the industry practices of pharmaceutical companies, and as such she is prohibited from testifying as to whether Novartis complied with industry standards."). This Court should do the same.

III. The Court Should Exclude Dr. David's "Hazard Analysis" and All Opinions Related Thereto.

Dr. David claims to have performed a "hazard analysis" on the Bair Hugger system, pursuant to a process "[a]dapted by Dr. Yadin David from Mitre, system engineering guide." (David Rpt. at 6 n.1 (ECF No. 316).) Based on this analysis, he theorizes regarding different mechanisms by which the Bair Hugger could feasibly pose an infection risk, and purports to conclude that "the device more likely than not contributes to infections during its use in orthopedic implant surgeries." (David Rpt. at 7-8.) Dr. David also contends Defendants should have performed a similar "hazard analysis" to identify potential Bair Hugger risks, but did not. (David Rpt. at 44.)

Dr. David's "hazard analysis" and related opinions should be excluded in their entirety because, as discussed in detail below, (1) he is unqualified to assess the Bair Hugger system for clinical risk, and (2) the methods he employed were unreliable.

A. Dr. David Is Unqualified to Assess the Bair Hugger for Clinical Risk.

Dr. David is unqualified to testify to his "hazard analysis" opinions on many levels. While he is a biomedical engineer, he is not a medical doctor or clinician (David Dep. at 247:13-16), and has no expertise in microbiology, aerobiology, epidemiology, biostatistics, or infectious disease (David Dep., at 51:19-21; 244:20-22; 245:22-246:3;

284:7-17). In addition, although a part of his "hazard analysis" opinions relates to the identification of *clinical risks* inherent to the Bair Hugger system when used in orthopedic surgeries, Dr. David repeatedly testified that his purpose was not to assess the Bair Hugger in the clinical context, and disclaimed any ability to identify clinical risks on his own.[5] Indeed, although he has long been part of a hospital committee that evaluates medical devices as part of his hospital-employer's purchasing-decision process, Dr. David relies wholly on *others* to identify the clinical benefits and risks of the products evaluated, and he does not evaluate them on his own. (David. Dep. at 307:3-9 (testifying he does not form clinical determinations on his own, but rather "ha[s] to receive the[] input" of various specialists before forming any conclusions as to risk or benefit), 309:3-7 ("Q. . . . In performing your work for the hospitals, did you rely on physicians and nurses to provide you with information about clinical risks and benefits? A. On the clinical side, yes.").) If Dr. David does not evaluate clinical risks on his own in his professional capacity, he is unqualified to do so in the context of litigation. *See Barrett v. Rhodia, Inc.*, 606 F.3d 975, 982–83 (8th Cir. 2010) (excluding engineering expert whose opinion included pinpointing the cause of Plaintiff's injury).[6]

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[5] (*See, e.g.*, David Dep. at 27:16-18 ("I did not seek to make any performance comparison or derive any clinical outcome of the device use."), 39:25-40:3, 44:11-13, 111:21-112:2, 119:16-22, 140:2-4, 278:18-19 ("I believe you're asking me a clinical question that was not my objective."), 279:2-5 ("[M]y charge was to look at the Bair Hugger 750 from hazard and risk control issues, not from clinical outcomes . . . .").)

[6] Because Dr. David is admittedly not a medical expert, his "opinion" as to medical causation is valuable only insofar as one of Plaintiffs' medical experts (Samet, Jarvis, or Stonnington) relies upon it to support an opinion that the Bair Hugger system can be "ruled in" as a potential cause. *See Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1210 (8th Cir. 2000) (the cause of medical injuries "requiring surgical intervention or other

Moreover, prior to his retention in this case, Dr. David had virtually *no experience* with the Bair Hugger system, or with any of the other patient-warming technologies that are the subject of his opinions in his Report. (*See* David Dep. at 11:4-17, 17:20-19:24, 20:5-8.) He has never substantively encountered the Bair Hugger system in his professional capacity (David Dep. at 19:15-24), and outside of the work he has done in this case, has never researched, operated, or otherwise examined Bair Hugger technology (David Dep. at 13:18-25, 17:3-19, 23:2-10, 201:22-202:16). Absent any special knowledge or expertise related to the Bair Hugger system, Dr. David is not qualified to opine to its "hazards" or clinical risks. *See Weisgram v. Marley Co.*, 169 F.3d 514, 521 (8th Cir. 1999) (expert not qualified to opine on product failure given inexperience with relevant products).

Similarly, Dr. David offers no special expertise in filter technology. He purports to have a "working knowledge" of filters based on his committee role in the design of operating rooms and evaluation of medical devices in the past; but he has never been responsible for selecting filter technology for any operating room, has never provided expertise with respect to filters and their effect on air, and has never conducted testing of a filter of any kind. (David Dep. at 230:13-235:20, 231:14-16.) Indeed, although several of his opinions depend upon the accuracy of his assertion that the 750 Series filter poses a greater infection risk than the 500 Series (*see* David Dep. at 262:13-20, 317:21-318:6),

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highly scientific technique for diagnosis . . . is not within the realm of lay understanding and must be established through expert testimony."); *see also Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 988-92 (8th Cir. 2001). Yet none of Plaintiffs' medical experts materially relies on Dr. David's opinions.

Dr. David never compared the two filters himself, and could not even provide basic information about their characteristics. (David Dep. at 315:20-317:15.) For example, he testified the 500 Series filter was a "square" when in fact it is a cylinder, and disclaimed knowledge of the filter's size. (David Dep. at 316:25-317:15.) Accordingly, Dr. David's lack of filter expertise likewise renders him unqualified.

B. Dr. David Employed Unreliable Methods in His "Hazard Analysis."

Dr. David's "hazard analysis" and related opinions should be excluded additionally because his methods were unreliable in several respects. As an initial matter, although he purports to reach conclusions as to medical causation based upon his work, Dr. David does not, and cannot, demonstrate that a "hazard analysis" is a scientifically valid method to get there. Even assuming it is, Dr. David did not employ a "hazard analysis" standard designed to address the clinical risks and benefits of medical devices. (David Dep. at 172:19-173:22.) Rather, he used his own "adapt[ation]" of a systems engineering standard (MITRE) that he had used in the hospital setting for disaster preparedness purposes. (*See* David Rpt. at 6 n.1; David Dep. at 169:8-172:13).[7] Dr. David does not explain why his "adapt[ation]" of this standard was an appropriate methodology to follow in this case, given he was aware of ISO 14971, knew it was used for risk management of medical devices, and yet chose not to apply it. (*See* David Dep. at 172:19-173:22; *see also* Tim Ulatowski Report at 86 (Ex. 3) (concluding Dr. David's

[7] *See also* MITRE Systems Engineering Guide, Risk Management and Approach, available at: https://www.mitre.org/publications/systems-engineering-guide/acquisition-systems-engineering/risk-management/risk-management-approach-and-plan.

"hazard analysis" was not "in a form or manner of an industry standard medical device hazard analysis consisting of a risk assessment and risk control evaluation.").)

Even setting his overall methodological shortcomings aside, the steps Dr. David took in his "hazard analysis" are unreliable in additional ways. For example, with regard to the product examination component of his analysis, Dr. David examined a *used* Bair Hugger system purchased from eBay.com, under conditions inconsistent with real-life operating rooms, and without even knowing whether it was a properly functioning device. (*See* David Dep. at 23:20-24, 28:16-29:20, 33:16-34:19, 110:3-113:3, 119:2-121:11.) Moreover, Dr. David's deposition testimony makes clear that his examination had an extremely limited purpose. He admits he "was not trying to have a device that simulated clinical utilization." (David Dep. at 39:25-40:3; *see also id.* at 23:20-23, 40:5-10.) Rather, his purpose was merely to gain familiarity with a product that he had never before encountered in his professional capacity:

> I need to very simply clarify the purpose of my examination of the device. I wanted to see how the device is built, how it's put together, where the components physically sit, where is the intake, where is the output, how you connect the blanket to it, and I did not seek to make any performance comparison or derive any clinical outcome of the device use.

(David Dep. at 27:10-18.) Accordingly, outside of an attempt to compensate for his lack of past experience with the Bair Hugger technology, Dr. David's device examination, by his own admission, played no substantive role in his "hazard analysis."

While Dr. David theorizes that the Bair Hugger system can feasibly lead to SSIs through either (a) disruption of the operating room ventilation system or (b) introduction of bacteria as a result of inadequate filtration, Dr. David has no relevant expertise in

either area (*see* subsection (A) above), and is simply parroting the theories reflected in the articles he reviewed. (*See* David Rpt. at 8.) In any event, a plausible mechanism alone is not sufficient to support his contention that the Bair Hugger increases the risk of SSIs. *See Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001) (plausible mechanism was insufficient basis for general causation where experts "failed to produce scientifically convincing evidence that Parlodel causes vasoconstriction"). Moreover, although Dr. David claims that the Bair Hugger 750 Series poses a heightened risk of infection relative to the 500 Series because of reduced filtration efficiency, Dr. David has no data to support this contention (let alone the requisite expertise). He has never personally compared the filters of the two devices (David Dep. at 315:20-317:15); he has never performed any filter testing (David Dep., at 231:14-16; 244:23-25); and he has never even seen the 500 Series filter in person, opting instead to rely upon a "drawing" and photos he observed from a brochure (David Dep. at 315:20-23). Moreover, Dr. David concedes he does not know how much of a change in filter efficiency is required to even make a difference. (David Dep. at 261:2-13, 263:23-264:17.) If he does not know how much the filter efficiency would need to drop in order to effect an actual change in clinical risk, he cannot possibly opine to a heightened clinical risk with regard to the 750 Series filter. *See In re Mirena IUD*, 169 F. Supp. 3d at 445 ("A legitimate scientist or engineer in the field, knowing he did not have reliable numbers for a stage of his analysis, would decline to reach a conclusion. Dr. Jarrell's proceeding when he knew he did not have the proper basis suggests that his 'methodology was aimed at achieving one result.'").

Dr. David also purports to rely upon his "Review of Literature" in concluding an infection risk is "credible" and has "potential" with the Bair Hugger (David Rpt. at 8, 27-31), but this step falls short as well. As discussed in Defendants' motion to exclude plaintiffs' engineering experts, Dr. David lacks the expertise to opine credibly on causation. Furthermore, he did not apply any reliable methodology in forming his opinions, and his "Review of Literature" involved the very same articles relied upon by Plaintiffs' other experts, which do not establish general causation. Like Plaintiffs' other experts, Dr. David attempts to draw conclusions that the authors themselves disclaimed, and which contradict the reasoned conclusions of the FDA and other reputable medical organizations, formed after reviewing the very same material. *See* FDA Safety Alert, "Forced Air Thermal Regulating Systems: Healthcare Provider Letter - Information About Use" (Aug. 30, 2017) (Ex. 4) (Noting that the use of "thermoregulation devices during surgery, including forced air thermoregulating systems [of which the Bair Hugger system is by far the most commonly used], have been demonstrated to result in less bleeding, faster recovery times, and decreased risk of infection for patients.").

Not only does Dr. David's "Review of Literature" fail to provide support for his conclusions, it also ignores scientific evidence that is contrary to his opinions. Although Defendants have set forth a great number of studies showing that the Bair Hugger system reduces the incidence of SSIs, and that the device has no higher incidence of SSIs than other patient warming devices, Dr. David's analysis does not address *any* of these articles. (David Rpt. at 27-31.)

Most notably, Dr. David ignores two articles that directly undermine his opinions, including one from the ECRI Institute concluding that "there is insufficient evidence to establish that the use of FAW systems leads to an increase in SSIs compared to other warming methods."[8] The absence of this publication highlights the selective nature of Dr. David's review, as he previously cited and relied upon it in an expert report disclosed prior to MDL consolidation. (9/28/2015 Report of Dr. Yadin David, at 6 (Ex. 6).)

Dr. David's analysis ignores a second article (Kurz et al.) concluding that "[h]ypothermia itself may delay healing and predispose patients to wound infections," and that "[m]aintaining normothermia intraoperatively is likely to decrease the incidence of infections complications" in colorectal surgery.[9] Dr. David concedes that articles, like this one, would be "relevant to [his] consideration" to the extent they reported "that the use of a forced-air warming device during surgery decreased the risk of surgical site infection." (David Dep. at 273:18-24.) But when pressed regarding why he did not consider the Kurz article in his analysis, Dr. David testified he "probably . . . did not see it" because "[t]he heading doesn't seem like something that would fall within my search," and that in any event, the findings were not relevant to his objective, which "was to look at the Bair Hugger 750 from hazard and risk control issues, not from clinical outcomes, the type of question you have for me." (David Dep. at 275:24-279:5.)

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[8] *Forced-Air Warming and Surgical Site Infections: Our Review Finds Insufficient Evidence to Support Changes in Current Practice.* ECRI Institute, Guidance Article (April 2013), at 124 (Ex. 5).

[9] *See* Kurz, et al., *Perioperative Normothermia to Reduce the Incidence of Surgical-Wound Infection and Shorten Hospitalization*, The New England Journal of Medicine (1996) (Ex. 7); David Dep. at 275:24-279:5.

The Court should not permit Dr. David to testify to opinions based upon a one-sided literature review that cherry-picks only the most favorable scientific articles. *See, Smith v. Rasmussen*, 249 F.3d 755, 758 (8th Cir. 2001) (expert may not opine "based on an indiscriminate literature review" that is "beyond the scope of [his] expertise"); *Lust by & Through Lust v. Merrell Dow Pharms.*, 89 F.3d 594 (9th Cir. 1996) (affirming exclusion of expert testimony on grounds, among others, that the expert had "'picked and chosen' from the scientific landscape"); *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425-26 (S.D.N.Y. Mar. 14, 2005) (excluding experts whose literature reviews overlooked studies contrary to their opinions and "discussed only the evidence they believed would advance the plaintiffs' position").

For all of these reasons, the Court should exclude Dr. David's "hazard analysis" and related conclusions in their entirety.

IV. The Court Should Exclude Dr. David's Opinions on Alternative Designs.

Dr. David also opines upon alternative designs to the Bair Hugger that he posits are feasible and safer. Section 7 of his Report addresses internal design projects conducted by Defendants that Dr. David assumes could have replaced the Bair Hugger. Section 8 considers other products on the market that he asserts are safer alternatives.

"An expert proposing safety modifications must demonstrate by some means that they would work to protect [those allegedly endangered] but would not interfere with the machine's utility." *Unrein v. Timesavers, Inc.*, 394 F.3d 1008, 1012 (8th Cir. 2005); *Thompson v. Zimmer Inc.*, No. 11-CV-3099 PJS/AJB, 2013 WL 5406628, at *6 (D. Minn. Sept. 25, 2013) (excluding expert's alternative design testimony as "too

speculative to be submitted to the jury" where expert did not present data or testing to support contention that alternatives would be safer without compromising device utility). Dr. David provides no such showing, rendering all of this testimony unreliable.

In discussing alternative designs, Dr. David first reviews company documents to suggest that Defendants suppressed feasible, safer alternative designs developed internally. (David Rpt. at 32-38 (ECF No. 316).) These internal designs come in three buckets: (1) attempts to design a device with a HEPA filter at the end of the Bair Hugger hose, known as "Project Ducky"; (2) attempts to coat the inside of the Bair Hugger hose with an anti-microbial coating; and (3) a series of "ideations" that 3M brainstormed that might have redesigned the Bair Hugger hose.

Notably, Dr. David focuses on the existence of these projects, but provides no analysis as to whether the technology would have, in fact, been feasible or safer. "The Eighth Circuit has held that it is appropriate for district courts to exclude expert testimony involving proposed design changes that have never been developed or tested." *Ehlers v. Siemens Med. Sols.*, USA, Inc., 251 F.R.D. 378, 385 (D. Minn. 2008); *see also Jaurequi v. Carter Mfg. Co.*, 173 F.3d 1076, 1084 (8th Cir. 1999) ("Willis has not attempted to construct or even draw the suggested device, much less test its utility as a safety device. . ."). Here, Dr. David puts forth no analysis as to whether any of Defendants' internal designs were viable. Indeed, he ignores contrary evidence on that point. (*See* 2/24/2017 K. Zgoda Deposition Tr. at 164:10-18 (testifying that incorporation of anti-microbial coatings "in production for companies" was "a technology or proof-of-concept idea at the time") (Ex. 8); 3/17/2017 W. Tan Deposition Tr. at 107:8-21, 110:24-111:10

(testifying that insertable filter, modular disposable hose, and self-cleaning system concepts were "really-out-of-this-world type of exploratory," were "just white space," and that these ideations were nothing more than "a brainstorming exercise") (Ex. 9).) The mere fact Defendants explored potential design changes to the Bair Hugger does not satisfy Plaintiffs' burden to prove such designs were actually feasible and safer.

Dr. David also points to products on the market as potential alternative designs—including the VitaHEAT UB3, the Berchtold Tablegard, the Stryker Mistral-Air Warming System, and the Cincinnati SubZero WarmAir. (David Rpt. at 38-43.) As an initial matter, this Court has already ruled that the VitaHEAT UB3 "is not a reasonable, safer alternative to the Bair Hugger" because it uses conductive warming technology, a "fundamentally different type[] of technology" than that used with the Bair Hugger. (3/6/2017 Order at 2 (ECF No. 249); *see also* 4/13/17 Order at 3-4 ("[I]t was not clear error to conclude that a forced-air warming device is a different product using different technology than a conductive heating device.") (ECF No. 304).) One of the other three alternative technologies proposed by Dr. David—the Berchtold Tablegard system—also relies upon conductive heating technology, and thus is similarly disqualified. (*See* David Rpt. at 39 (noting the Tablegard system provides "conductive warming with no introduction of airflow to the sterile field or contact with the patient's skin.").)

With regard to the remaining two devices identified as feasible alternatives, Dr. David has no basis to opine, and makes no showing whatsoever, that either of these devices is actually safer. He did not examine either device, and never has in the course of his professional work. (David Dep. at 159:5-160:19.) And while he does purport to

identify unique characteristics of each—based on his review of publicly available marketing material and 510(k) summaries—his conclusions that these characteristics render the devices safer than the Bair Hugger are nothing more than bald assertions. Dr. David provides no data showing the incidence of SSIs with these devices is any lower, or different, than that associated with the Bair Hugger system. Indeed, he concedes he *has no such data*. (*See* David Dep. at 282:18-283:6.)

By contrast, recently published data from the Cleveland Clinic strongly suggests that the increased filtration of competing forced-air warming products—including with the Mistral-Air Warming System (one of Dr. David's proposed alternative designs)—confers *no* patient benefit whatsoever. Curtis et al. reviewed the Cleveland Clinic's patient database to compare hip and knee arthroplasty infection rates before and after the Clinic switched from Bair Hugger to the Mistral Air, a competing forced-air warming device that incorporates a HEPA filter, and which David points to as an "alternative design." (Curtis 2017 abstract (Ex. 10).) Notwithstanding the increased level of filtration in the Mistral Air, there was no statistically significant change in the overall infection rate between the two products; in fact, there was a non-significant *increase* in deep-joint infection rate (0.47% versus 0.77%) following the switch. *Id.* These results strongly support the conclusion that HEPA filtration is unnecessary for forced-air warming devices and does not provide any benefit to patients.

Dr. David also fails to show that the characteristics of his proposed "alternative" designs could be integrated into the Bair Hugger system without impacting its function. This is fatal to admissibility. *See Thompson*, 2013 WL 5406628, at *6 (excluding

engineering expert's alternative design opinions where expert made no showing that the alternatives were actually safer or that design changes would not compromise function of product); *see also Young v. Pollock Eng'g Group, Inc.*, 428 F.3d 786, 790 (8th Cir. 2005) ("Testimony may be excluded if an expert fails to explain how a proposed safety modification would protect the machine's operators without compromising the machine's utility."); *Unrein*, 394 F.3d at 1012 ("An expert proposing safety modifications must demonstrate by some means that they would work to protect the machine operators but would not interfere with the machine's utility.").

For all of these reasons, the Court should exclude Dr. David's opinions as to feasible alternative designs.

V. The Court Should Exclude Dr. David's Opinions as to Defendants' Motives, Intent, and State of Mind.

Dr. David in his Report purports to opine on the state of mind of Defendants in their design and marketing of the Bair Hugger system. (*See, e.g.*, David Rpt. at 44 (ECF No. 316) (opining that Defendants "consciously failed to meet" is obligations to provide information to healthcare community, and "willfully failed to meet its obligations to adequately ensure patient safety").) If Plaintiffs' briefing up to this point is any indication, Plaintiffs are likely to attempt to elicit such testimony from Dr. David at trial. (*See, e.g.*, Pfs.' Mem. in Supp. of Mot. to Amd. at 10-12, 19-20 (purporting to establish Defendants' state of mind and intent based upon opinions of Dr. David) (ECF No. 311).)

It is well-established that "[e]xpert testimony on the intent, motives, or state of mind of corporations . . . and others ha[s] no basis in any relevant body of knowledge or

expertise." *Kruszka*, 28 F. Supp. 3d at 931, 937; *see In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d at 547 ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony."). Accordingly, courts routinely exclude expert testimony regarding parties' intent, motive or state of mind. *See, e.g.*, *Kruszka*, 28 F. Supp. 3d 920; *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1069 (D. Minn. 2007). The Court should do the same here.

THE COURT SHOULD EXCLUDE DR. DAVID IN THE MINNESOTA STATE PROCEEDINGS

Minnesota Rule of Evidence 702 governs the admission of expert opinions in the Minnesota state proceedings, and requires: (1) that the witness be qualified as an expert "by knowledge, skill experience, training, or education," (2) that the expert testimony be helpful to the trier of fact; and (3) for scientific principles, that the proposed testimony satisfy the *Frye–Mack* standard. Minn. R. Evid. 702; *Doe v. Archdiocese of St. Paul*, 817 N.W.2d 150, 164 (Minn. 2012); *Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000). With regard to the latter requirement, the so-called *Frye-Mack* standard has two prongs. The first requires the proponent to demonstrate that the scientific opinions and technique be "generally accepted within the relevant scientific community"—in other words, that "experts in the field widely share the view that the results of scientific testing are scientifically reliable." *State v. Roman Nose*, 649 N.W.2d 815, 818-19 (Minn. 2002). Under the second prong, the scientific technique at issue must have "a foundation that is scientifically reliable." *Id.* at 818. That is, the proponent must "establish that the test

itself is reliable and that its administration in the particular instance conformed to the procedure necessary to ensure reliability." *Doe*, 817 N.W.2d at 165.

I. Dr. David's Opinions Fail to Satisfy the Qualification and Foundational Reliability Factors of Minn. R. Evid. 702 and *Frye-Mack*.

The Court should exclude Dr. David's opinions and testimony in the Minnesota proceedings, first, because they fail to satisfy the qualification and foundational reliability requirements of *Frye-Mack*. For the same reasons discussed above in the context of *Daubert*, Dr. David is not qualified to testify to his regulatory opinions, his opinions on the medical device industry standard of care, or any opinions as to the clinical risks posed by the Bair Hugger system. In addition, neither Dr. David nor Plaintiffs have established foundational reliability for his "hazard analysis" opinions, his alternative design opinions, or any opinions as to the Defendants' motives, intent, or state of mind. Accordingly, for the same reasons discussed above in the context of *Daubert*, the Court should exclude Dr. David's opinions entirely in the Minnesota proceedings.

II. Dr. David's Opinions and Techniques Are Not Generally Accepted.

Dr. David's opinions and testimony are additionally inadmissible in the Minnesota state proceedings because they are not generally accepted. Where scientific principles are at stake, Minnesota courts require proponents of expert testimony to prove that that the scientific technique or principle at issue is "generally accepted within the relevant scientific community"—in other words, that "experts in the field widely share the view that the results of scientific testing are scientifically reliable." *State v. Roman Nose*, 649 N.W.2d 815, 818-19 (Minn. 2002). For all of the reasons discussed above, Plaintiffs can

make no such showing with respect to Dr. David's opinions. Accordingly, on these grounds too, the Court should exclude Dr. David in the Minnesota proceedings.

CONCLUSION

For all of the reasons discussed above, the Court should exclude Dr. David's opinions in their entirety, in both the federal MDL and Minnesota state proceedings.

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Respectfully submitted,

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